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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/628,803	07/28/00	MURPHY J	112910.3302

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EXAMINER

HUI, S

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 02/14/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/628,803

Applicant(s)

MURPHY ET AL.

Examiner

San-ming Hui

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-33 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claims 1-20 and 33, drawn to a method for alleviating stuttering comprising administering a gamma-aminobutyric acid (GABA) receptor modulator, classified in class 514, subclass 96, 100, 111, 182, 220, 270, 210.16, 211.09, 300, 179, 567, and 661.
- II. Claim 21, drawn to a method for alleviating stuttering comprising administering a gamma-aminobutyric acid (GABA) receptor modulator and additional active ingredient, classified in class 514, subclass 96, 100, 111, 220, 300, 270, 210.16, 211.09, 179, 182, 567, and 661.
- III. Claims 22-32, drawn to a pharmaceutical composition for alleviating stuttering, classified in class 514, subclass 96, 100, 111, 182, 220, 270, 300, 210.16, 211.09, 179, 567, and 661.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation for example, the invention of Group I utilizes one

gamma-aminobutyric acid (GABA) receptor modulator, the invention of Group III is a combination of gamma-aminobutyric acid (GABA) receptor modulator and an additional active ingredients for alleviating stuttering. The invention of Group III operates differently than Group I because it has two active ingredients instead of one.

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation for example, the invention of Group I utilizes one gamma-aminobutyric acid (GABA) receptor modulator, the invention of Group II utilizes a combination of gamma-aminobutyric acid (GABA) receptor modulator and an additional active ingredients. The invention of Group II operates differently than Group I because it has two active ingredients instead of one.

Inventions III and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the gamma-aminobutyric acid (GABA) receptor modulator combination as claimed such as diazepam can be used in a materially different process of using the same combination such as status epilepticus treatment.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

### ***Election of Species***

Claims 1-18, 20-32 are generic to a plurality of disclosed patentably distinct species comprising for Group I: a gamma-aminobutyric acid (GABA) receptor modulator or for Group II and III: a gamma-aminobutyric acid (GABA) receptor modulator and a second active agent.

Patentably distinct species of gamma-aminobutyric acid (GABA) receptor modulators are recited in the claims for example, alphaxalone which is classified in Class 514, subclass 179; allopregnanolone which is classified in Class 514, subclass 182; alprazolam which is classified in Class 514, subclass 220; amobarbital which is classified in Class 514, subclass 270; baclofen which is classified in Class 514, subclass 567; cloflubicyne which is classified in Class 514, subclass 661; and pagoclonone which is classified in Class 514, subclass 300. Moreover, the patentably distinct species also comprising a GABA receptor modulators having a structure that is represented by formula I, for example:

When  $R_1$  and  $R_2$  composed a phosphorous containing ring,  $R_3$  is alkyl,  $X_1$  and  $X_2$  composed a cycloalkyl ring, and  $X_3$  is a methylene group, it is classified in Class 514, subclass 111.

When  $R_1$  and  $R_2$  composed a oxygen containing ring,  $R_3$  is alkyl,  $X_1$  and  $X_2$  composed a cycloalkyl ring, and  $X_3$  is a  $-N(R_5)$  group, where  $R_5$  is phosphorous, it is classified in Class 514, subclass 100.

When  $R_1$  and  $R_2$  composed a sulfur containing ring,  $R_3$  is alkyl,  $X_1$  and  $X_2$  composed a cycloalkyl ring, and  $X_3$  is a  $-N(R_5)$  group, where  $R_5$  is phosphorous, it is classified in Class 514, subclass 96.

When  $R_1$  and  $R_2$  composed a four-member nitrogen containing ring,  $R_3$  is alkyl,  $X_1$  and  $X_2$  composed a cycloalkyl ring, and  $X_3$  is a methylene group, it is classified in Class 514, subclass 210.16.

When  $R_1$  and  $R_2$  composed a seven-member nitrogen containing ring,  $R_3$  is alkyl,  $X_1$  and  $X_2$  composed a cycloalkyl ring, and  $X_3$  is a methylene group, it is classified in Class 514, subclass 211.09.

Due to the structural diversity of the active compounds encompassed by the claims and the corresponding diversity oin the field of search as noted above, the search for all species of each presents an undue burden on the office. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for each of A) a gamma-aminobutyric acid (GABA) receptor modulator if the invention of Group I is elected or B) a gamma-aminobutyric acid (GABA) receptor modulator and a specific second active agent if the invention of Groups II or III is elected, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the

record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because the above restriction/election requirement is complex, a telephone call to applicant's agent to request an oral election was not made. See M.P.E.P. Sec. 812.01. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

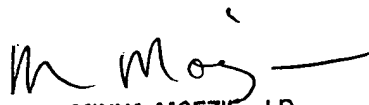
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Monday to Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui  
February 12, 2001

  
MINNA MOEZIE, J.D.  
SUPERVISORY PATENT EXAMINER  
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